REMARKS

The extant claims now are 1-23 and 25-26.

A terminal disclaimer vis-à-vis USP 6,635,279 is filed herewith. Accordingly, the examiner's double patenting rejection

The rejections under 35 USC § 112

Preliminarily, the examiner is thanked for his kind suggestion regarding the wording of claim 10. The typographical error, called to applicants' attention by the examiner, has been corrected.

The claims no longer use the language "such as" but rather conventional *comprising.* Of course, under the doctrine of equivalents, the claims protect against the use of any reasonable equivalent.

Claim 20 has been cast in Jepson form which should be clearly understood. As explained in *In re Hanson*, 332 F.2d 825, 141 USPQ 803 (CCPA 1964), the purpose of Jepson claim is to avoid unnecessary verbiage in describing what the skilled worker already knows. Their use is "admirable. *In re Sutherland*, 347 F.2d 1009, 146 USPQ 485, 489 (CCPA 1965). See also *In re Skrivan*, 166 USPQ 85, 88 (CCPA 1970).

Accordingly, it is submitted that the claims now properly define the invention under the provisions of 35 USC §§112, first and second paragraph.

The rejections under 35 USC § 102(b)

A. Goertz et al. (US 4,901,460)

Ortega (US 4,837,032). Applicants' invention is clearly novel over Goertz et al. Examples 1 and 3 (referred to by the examiner) of the reference do not employ dosage

forms including "formulated" mixtures of polyvinyl acetate (PVAc) and polyvinyl pyrolidone (PVP). Rather, Goertz et al. teaches *copolymers* of PVAc and PVP. Such a copolymer is chemically and physically different from a mixture of the (essentially) homopolymers of PVAc and PVP.

B. Ortega (US 4,837,032)

In applicants' formulated mixture of PVAc and PVP, the PVP is finely dispersed in the PVAc (see page 8, lines 44-46). This formulated mixture is significantly different from the physical mixtures discussed by Ortega. Applicants' resulting granules must have a different structure compared to granules where a physical mixture is used.

Significantly, according to the examples of Ortega, 70 to 76% of the active substance are released after 6 hours and 90% are released after 8 hours (see table I and II). According to the instant invention only about 40% are released after 6 or 8 hours (as note, inter alia, table 6).

The rejections under 35 USC § 103(a)

The references as cited by the examiner fail to make out the necessary prima facie case for obviousness.

Regarding the rejection of claims 1-7 and 9-16 under § 103 over Ortega it should be noted that there is not indication whatsoever in the Ortega document that formulated mixtures of PVP and PVAc might be used in a process which is not a wet granulation process.

The wet granulation process as disclosed by Ortega for instance in example 1 needs more steps and therefore is not time- and cost-effective.

The presently claimed process wherein an active ingredient, the formulated mixture and optionally additional components are processed to granules in the absence of a granulating fluid is not only simpler and cost-effective, but also produces tablets with excellent properties with regard to slow release and tablet hardness. Also tablet hardness is not dependant on the particle size of the granules (see Table 5). This makes the process much more efficient and safe.

It was not to be expected by the skilled worker that by using a formulated mixture of PVP and PVAc and granulating the components at elevated without the need for a granulating liquid tablets with improve release profiles and good hardness could be obtained. Insofar Ortega's disclosure cannot render obvious the claimed process.

Regarding the rejection over Ortega in view of Noda we would again note that the excipients disclosed by Noda considered in combination with Ortega's teaching would not lead the skilled person to the claimed process and product.

Accordingly, allowance is respectfully solicited.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such deposit account.

Respectfully submitted,
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COMPLETE LISTING OF ALL CLAIMS IN THE APPLICATION

1. (currently amended) A process for producing an oral dosage form with sustained realease of active ingredient, comprising

   a) a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone

   b) at least one active ingredient

   c) optionally water-soluble polymers or low or high molecular weight lipophilic additives

   d) and, optionally, excipients,

   wherein the mixture of a) to d) or a) to c) or a) and b) and d) or a) and b) is granulated by heating to from 40° to 130°C, and

   wherein the molecular weight of polyvinylpyrrolidone is between 20,000 and ~~10,000,000~~ 1 000 000 and wherein the formulated mixture of polyvinylacetate and polyvinylpyrrolidone acts as binder and a matrix former.

2. (previously presented) A process as claimed in claim 1, wherein the polyvinyl acetate to polyvinylpyrrolidone ratio is 6:4 to 9:1.

3. (previously presented) A process as claimed in claim 1, wherein the active ingredient: water-soluble polymers or low or high molecular weight lipophilic additives ratio employed is from 5:95 to 85:15.

4. (previously presented) A process as claimed in claim 1, wherein the polyvinyl acetate and polyvinylpyrrolidone each have a molecular weight of from 20,000 to 1,000,000.

5. (previously presented) A process as claimed in claim 1, wherein the mixture is granulated by heating to from 45 to 100°C.

6. (previously presented) A process as claimed in claim 1, wherein the particle size of the active ingredients employed is in a range from 20 to 700 µm.

7. (previously presented) A process as claimed in claim 1, wherein the excipients employed are fillers, disintegrants and adsorbents, lubricants, flowability agents, dyes, stabilizers, antioxidants, wetting agents, preservatives, release agents, flavorings or sweeteners.

8. (previously presented) A process as claimed in claim 1, wherein fillers are selected from the group consisting of lactose, cellulose powder, mannitol, calcium diphosphate and starch are employed as excipients.

9. (previously presented) A process as claimed in claim 1, wherein the granules can be produced by employing the process of mixer granulation, fluidized bed granulation or extrusion granulation.

10. (currently amended) A process as claimed in claim 1, wherein the production is ~~possible~~ both continuously and batchwise.

11. (previously presented) A process as claimed in claim 1, wherein further processing of the granules, principally the forced screening, can take place both in the hot state and in the cooled state.

12. (previously presented) A process as claimed in claim 1, wherein besides the formulated mixture of polyvinyl acetate and polyvinylpyrrolidone, further release-sustaining excipients may optionally be employed before, during or after the

granulation.

13. (previously presented) A process as claimed in claim 1, wherein water-soluble, water-soluble highly swelling or lipophilic excipients are employed for further modification of release.

14. (currently amended) A process as claimed in claim 1, wherein the water-soluble highly swelling substances employed are alginates, pectins, galactomannans, carrageenans, dextran, curdlan, pullulan, gellan, chitin, gelatin, xanthans, hemicelluloses, cellulose derivatives ~~such as~~ comprising methylcellulose, hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, carboxymethylcellulose, starch derivatives ~~such as~~ comprising carboxymethylstarch, degraded starch, maltodextrins, polyacrylic acid, polymethacrylic acid, acrylic acid/methacrylic acid copolymers, polyvinyl alcohols, high molecular weight polyethylene glycols, polyoxyethylene/polyoxypropylene block copolymers, high molecular weight polyvinylpyrrolidones and derivatives thereof.

15. (currently amended) A process as claimed in claim 1, wherein the lipophilic substances employed are fatty alcohols consisting essentially of stearyl alcohol, fatty acids selected from the group consisting essentially of such as stearic acid, glycerides, fatty acid esters and fatty alcohol esters, lipophilic polymers selected from the group consisting essentially of ethylcellulose, cellulose acetate, acrylic ester/methacrylic ester copolymers, methacrylic acid/acrylic ester copolymers, cellulose acetate phthalate, cellulose acetate succinate,

hydroxypropylmethylcellulose acetate phthalate and hydroxypropylmethylcellulose acetate succinate.

16. (previously presented) A process as claimed in claim 1, wherein the water-soluble polymers are selected from the group of: polyvinyl alcohols, polyethylene glycols, polyoxyethylene/polyoxypropylene block copolymers, polyvinylpyrrolidones vinyl acetate/vinyl pyrrolidone copolymers, polyethylene glycols, polyvinylpyrrolidones, vinyl acetate/vinylpyrrolidone copolymers or maltodextrins, and salts thereof.

17. (currently amended) An oral dosage form comprising

a) a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone

b) at least one active ingredient

c) optionally water-soluble polymers or low or high molecular weight lipophilic additives

d) and, opitonally excipients,

wherein the mixture of a) to d) or a) to c) or a) and b) and d) or a) and b) is granulated by heating to from ~~40%~~ 40° C to 130°C

18. (previously presented) An oral dosage form as claimed in claim 17, which comprises as active ingredients food supplements or additives, vitamins, minerals or trace elements or active pharmaceutical ingredients.

19. (previously presented) An oral dosage form as claimed in claim 18, which comprises active pharmaceutical ingredients as active ingredients.

20. (previously presented) An oral dosage form as claimed in claim 18, wherein the

active pharmaceutical ingredient is selected from the group of benzodiazepines, antihypertensives, vitamins, cytostatics, anesthetics, neuroleptics, antidepressants, antibiotics, antimycotics, fungicides, chemotherapeutics, urologicals, platelet aggregation inhibitors, sulfonamides, spasmolytics, hormones, immunoglobulins, sera, thyroid therapeutics, psychopharmaceuticals, antiparkinson agents and other antihyperkinetics, ophthalmologicals, neuropathy products, calcium metabolism regulators, muscle relaxants, lipid-lowering agents, liver therapeutics, coronary agents, cardiac agents, immunotherapeutics, regulatory peptides and their inhibitors, hypnotics, sedatives, gynecologicals, antigout agents, fibrinolytics, enzyme products and transport proteins, enzyme inhibitors, emetics, perfusion promoters, diuretics, diagnostics, corticoids, cholinergics, biliary therapeutics, antiasthmatics, bronchospasmolytics, beta-receptor blockers, calcium channel blockers, ACE inhibitors, arteriosclerosis remedies, antiinflammatory agents, anticoagulants, antihypotensives, antihypoglycemics, antifibrinolytics, antiepileptics, antiemetics, antidotes, antidiabetics, antiarrhythmics, antianemics, antiallergics, anthelmintics, analgesics, analeptics, aldosterone antagonists, weight-reducing agents.

21. (previously presented) An oral dosage form as claimed in claim 17, which is used to produce compressed tablets.

22. (previously presented) A drug product with delayed release of active ingredient, which is an oral dosage form as claimed in claim 17.

23. (previously presented) A drug product for delayed release of active ingredient,

which is an oral dosage form as claimed in claim 17 which has been produced by compression.

24. (canceled)

25. (previously presented) The method of delaying the release of at least one active ingredient comprising producing the oral dosage form of claim 17 wherein the at least one active ingredient comprises food supplements or additives, vitamins, minerals or trace elements.

26. (new) In a process for delaying the release of active ingredients in dosage form, the improvement wherein the dosage from is that of claim 17.